

USER'S MANUAL



iMate-II Cordless Endo Motor

*The unit must be installed by a qualified engineer.

*Only for user by dental professionals.

*Read this operation manual carefully before installation or operation.

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REMARKS:

The pictures here are for reference only.

Real products shall prevail.

The parameters and pictures in this manual are subject to change without prior notice.

Thank you for purchasing our device. Before operating the device, please fully read the manual and this manual should be saved for later use.

DENJOY DENTAL CO., LTD will take the responsibility for the security, reliability, capability under the following conditions:

1. The installation, debugging, maintenance should be adjusted by the approbatory technician by our company or obtained related nation quality level license professions.
2. The power supply shall be in conformity with the relevant provisions of the state and the use requirements of device itself.
3. The device should be operated by licensed dental professionals with medical applied skill. The whole operation process should follow user's manual strictly.

DENJOY DENTAL CO., LTD has right to improve shape and structure of the device, change any information and technical specification of this manual all the time, and no need to notice the user in advance.

CONTACT INFORMATION

The device is manufactured by:

DENJOY DENTAL CO., LTD

Address: F4, Building A4, Lugu Medical Device Park, No.229
Guyuan Road, Changsha, 410205 P. R. China

Authorized European Representative:

Company name: LANDLINK GMBH

Address: DORFSTRASSE 2/4, EMMENDINGEN, 79312 GERMANY

Please contact sales representative directly from whom you have bought this device for user's record and further after-sale service.

SECTION 1: GENERAL INTRODUCTION

Cordless Endo Motor is an endodontic operation instrument. Endo motor function is a kind of endodontic micromotor to drive Ni-Ti instruments, which can assist the dentists to shape more standard root-canal in the process of root-canal treatment based on the micro-electronic control technology. Cordless endo motor can be held in hand to operate and cordless charging. This unit contributes to alleviate the dentist's working intensity.

Product application and intended use

Cordless Endo Motor is applied to dental especially endodontic treatment. It is used for treat the root canal pulp necrosis, chronic pulpitis, chronic apical periodontitis (including meat tooth apical swelling, periapical abscess, periapical cyst), periodontal pulp syndrome and systemic diseases should not be extract but urgent needed to be treat.

Unique advantages

Use endo rotary file to machinery enlarge the root canal, Not only enlarges to the root canal in straight situation, but also works for curved root canal.

1, Compact design complies with standard of human engineering, exquisite and ingenious of surface, easy to take.

2, 6 different program (Can be memorized) which can be preset according the requirement of the operator.

3, Auto-reverse and auto-stop function: When torque exceeds the upper limit, the file will automatically reverse or stop.

4, Mini 16: 1 Contra angle can be 135°C autoclaved.

5, Build-in Rechargeable battery, greatly resolved the inconvenience of **frequently replace the battery and the cost of using our device.**

In order to protect the life-span and working life of the battery. The machine will turn off automatically after 5 minutes of no-operation.

6, If low battery, the machine will alarm to indicate operator.

7, Cordless charging makes the whole process safer.

SECTION 2: MAIN TECHNICAL INDEX

Model Name: iMate-II

Trade Name: iM2C

Degree of protection against electric shock:

- Type B applied part: 

Degree of protection against ingress of water: IPX1

Operation mode: Continuous Operation

Main Unit

Battery voltage: 3.7Vdc

Battery capacity: 1050mAh

Net weight: 210 g

Adapter













Rated input voltage: AC100-240V 50HZ/60HZ




Output voltage: DC5V

Output current: 1A

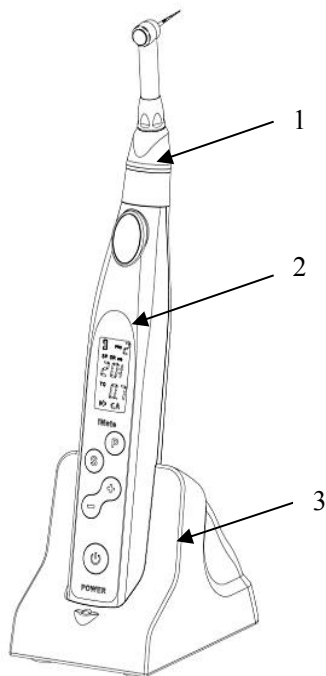
SECTION 3: SYMBOL

The following symbols may appear in this manual, on the label, or on its accessories. Some of the symbols represent standards and compliances associated with the endo motor and its use.

	Consult accompanying documents
	Caution: Consult accompanying documents
	Authorized Representative in the European Community
	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
SN	Specifies serial number
	Type B applied part
	Refer to instruction manual / booklet
	The device should not be used after the end of the shown or the day
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	alert indicator displayed on the LCD screen
	Battery power sign displayed on the LCD screen

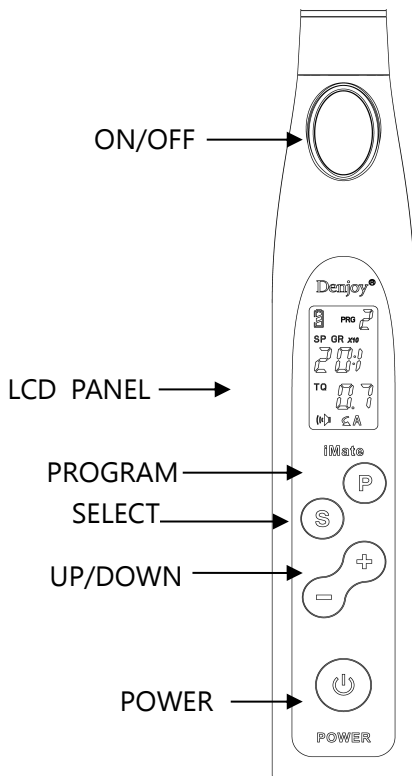
	AUTO REVERSE: If the load is removed after auto reverse rotation, it returns to the normal rotation again.
	AUTO STOP: If the load is removed after auto reverse rotations, it stops.
	AUTO REVERSE OFF: Auto reverse function is not activated.

SECTION 4: PRODUCT STRUCTURE



1. Mini 16: 1 HP Contra Angle 2. Main Unit 3. Charging Base

SECTION 5: OPERATION PANEL AND LCD SCREEN



OPERATION PANEL

POWER

- Holding down the POWER key for more than one second turns on the power and the LCD panel lights.

- Holding down the POWER key for more than one second while the power is on turns off the power and the LCD display turns off.

ON/OFF

When the power is on, press ON/OFF key and the device start working, press this key again and the device stop working.

SELECT



To change Torque (TQ), Gear Ratio (GR), Speed (SP) and Auto reserve setting. The speed and torque can be changed while the file is in motion.

PROGRAM (MEMORIZE)



The present program number can be displayed.
The program number is available from 1 to 6.
Holding down the PROGRAM key for more than one second choose program number.

The following parameters can be set.

Torque, Gear Ratio, Speed and Auto reserve.

Press PROGRAM key can memorize the parameters setting.

UP/DOWN



To adjust the set value for each parameter

Speed: rpm, Torque: N.CM

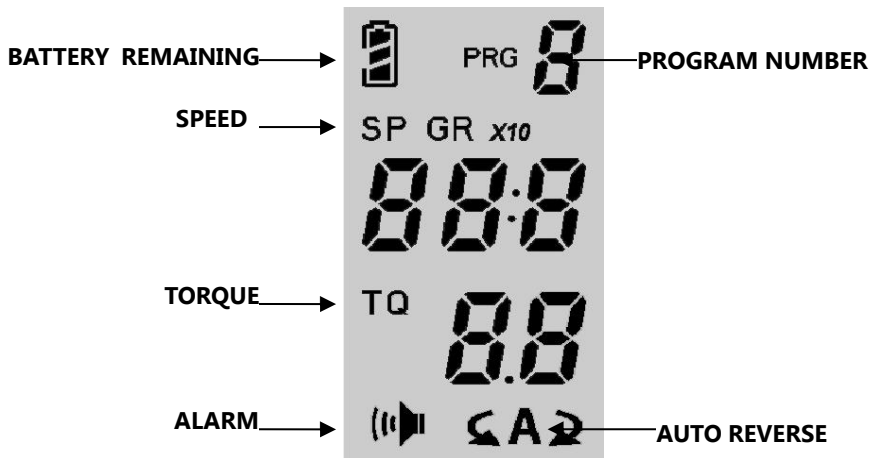
Gear can be selected on 10:1, 16:1, 20:1.

Please use the suitable contra angle based on gear ratio.

Speed (rpm)	Gear Ratio	Torque (N.CM)
200-900	10:1	0.2~2.2

140-550	16:1	0.3~3.0
100-450	20:1	0.4~4.0

LCD PANEL



AUTO REVERSE

The present auto reverse mode mark is displayed.

↶A↷ : AUTO REVERSING (If the load is removed after auto reverse rotation, it returns to the normal rotation again.)

A↷ : AUTO STOP (If the load is removed after auto reverse rotations, it stops..)

↷ AUTO REVERSE OFF: Auto reverse function is not activated.

BATTERY REMAINING

The mark of the present remaining amount of the batteries is displayed regardless of the ON or OFF position of the power. The mark will be animated when the batteries are being charged.



:Means full charge



:Means approx. 30-80% remains




: Means less than 30%



: Means low voltage. Charge immediately

Initialization of Program (Factory-set configuration)

The program can be returned to the original state configured at the time of factory shipment, if setup becomes confusing.

1. Turn on the power when the power is off.
2. Connect handpiece contra angle
3. Hold down the SELECT key  for more than one second
4. Press ON/OFF key when the LCD panel indicates "CAL"
5. Initialization is completed, when LCD panel display normally.

SECTION 6: OPERATION

1, Charge

A, connect the power adapter to the charging base.

B, Put the main unit on the charging base, during this period, please confirm if a beep is heard and the power display is flashing.

C, If the beep has been heard, and the Power display shows "FUL", means the battery is full.

2, Contra angle install and uninstall

Connect the contra angle and main unit, please target the hole of main unit and contra angle until a sound can be heard. When uninstall the contra angle, please pull out in vertical direction.

3, The intall and uninstall of bur

Insert the bur inside the contra angle and revolve lightly to find the contra angle right position, and then use stronger strength to insert until a sound can be heard. When uninstall the bur, just press the pushbutton contra angle to uninstall.

Note:

While uninstll the bur, please turn off the power.

While install the bur, please double confirm the bur has been successfully loaded.

Please keep the bur clean, dirty bur can cause the vibration during the operation.

4, Operation:

Press the power button to start the machine, press the engine on/off button to start the rotation, press again the engine on/off button to stop the rotation.

5, After the operation, - - - - -

Please press the power button to turn off the machine after the operation.

Auto turn off function

The machine will automatically turn off after 5 minutes of no-use.

Program memory setting.

Because last time you already saved the program setting, this program setting will remain the same until you change the program and save again.

SECTION 7: NOTICE

Note: Please do not use improper bur because it will cause accident during operation.

Please use the speed according to the bur manufacturer.

Please avoid putting the machine under high temperature such as sun light, fire.

While insert the machine to the charging base, please make sure to put in the correct position in order to avoid break.

Please do not lubricate our Endo motor or autoclave it.

The endo motor is not water proof, please keep it away from water or medicine liquid in order to avoid short circuit.

Please do not fall down the main unit and charging base.

Please use our power adapter for charge the machine.

Our endo motor usually will not make electromagnetic interference other

equipment

Forbidden

The cardiac pacemaker patient can not use this product.

Do not use with high-frequency surgical equipment and heart disease in patients with caution!

The machine can only be used independently; please do not connect the machine with other products.

Section 8: TROUBLESHOOTING GUIDE

When trouble is found, check the following again before contacting your dealer. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your dealer.

Problems	Cause & Solution
The power is not turned on	The batteries are empty. Charge the batteries or use the AC adapter.
	The press of the power button is short. Please long press the power button
	The POWER button is broken. Contact with your dealer.
The battery can't be charged.	The adapter didn't connect well. Please recheck the connection
	The major machine didn't put on the charger base correctly. Please recheck the connection
	The battery is broken. Contact with your dealer

SECTION 9: MAINTENANCE

1) Please recharge the battery for 5 minutes each month and check the machine everything in order too.

2) The machine has the life span for 5 years.

3) When the surface of main body is polluted, please rub the surface with dry soft cloth ONLY by use Neutral cleanser

REMARKS: Any liquid lotion like ethanol, banana oil and light oil are not allowed.

SECTION 10: STERILIZATION

Please autoclave HP contra angle only.

Before autoclave contra angle, please use AR spray for cleaning the contra angle.

The mentioned above accessories we suggest use 135°C autoclave for 15 minutes. 121°C autoclave for 20 minutes.

If the cleaned contra angle is not in use, please seal in the sterilization bags and store it in a clean place.

Remarks:

Please autoclave HP contra angle only.

Because the high temperature disinfection stand is close to the bottom of the heat source, the local temperature will be very high, so put the vessel in the middle or upper part of the disinfection cabinet.

Oxidation potential water, (strongly acidic water super acidic water) or sterilization liquid is strictly prohibited to wash, impregnation the vessel.

Section 11: ENVIRONMENTAL REQUIREMENTS

OPERATING CONDITIONS

Ambient temperature: +5°C ~ +40°C

Relative humidity range: ≤80%

Atmospheric pressure: 50kPa~ 106kPa

STORAGE AND SHIPPING CONDITIONS

Ambient temperature: -10°C ~ +50°C

Relative humidity range: ≤80%

Atmospheric pressure: 50~106kPa

Equipment is not suitable for storage in the presence of sunlight, rain, dust, and corrosive gasoline and volatile without poor ventilation.

Transportation is applicable to all common method.

Section 12: Packing List

ENDO MOTOR iMate-

I I includes: Main body	1 pc
Charging base	1 pc
Mini 16: 1 HP contra angle	1 pc
Adapter	1 pc
Motor cover	1 pc
Use manual	1 pc

SECTION 13: WARRANTY STATEMENT

The device is maintained free of charge and doesn't require any routine maintenance within warranty period.

Do not modify and disassemble the device.

This instrument described below has been fully inspected and confronts to the current products specification.

This device is guaranteed for its designated use, against original defects in materials and workmanship for a period of 12 months from date of purchase.

Products warranty or service will not be extended if (1) the **product is repaired, modified, misused, disassembled, or using the** parts are not provided by the manufacturer, (2) The serial number of the product is defaced or missing.

The guarantee for accessories is 6 months. All accessories of the device are damaged or needed to be renewed, the user can purchase new accessories from the seller.

WARNING

The device is not repairable by user and contains no user serviceable parts. No modification of this equipment is allowed.

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

The manufacturer does not require such preventive inspections by other persons.

Please contact sales representative directly from whom you have bought this device for user's record and further after-sale service.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
<p>The [iMate- I] is intended for use in the electromagnetic environment specified below. The customer or the user of the [iMate- I] should assure that it is used in such an environment</p>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The [iMate- I] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class [B]	<p>The [iMate- I] is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:</p> <p>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [iMate- I] or shielding the location.</p>
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration - electromagnetic emissions			
<p>The [iMate- I] is intended for use in the electromagnetic environment specified below. The customer or the user of the [iMate- I] should assure that it is used in such an environment</p>			
Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. The electrical fast transient burst (EFT) is generated by the switching of inductive loads. Separation between the equipment and other loads shall be considered before installation. Mains filter is required, if necessary.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short	<5% U_T (>95% dip in	<5% U_T (>95% dip in	Mains power quality should be that of a

interruptions and voltage variations on power supply input lines IEC 61000-4-11	U_T for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5s	U_T for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5s	typical commercial or hospital environment. If the user of the [iMate- I] requires continued operation during power mains interruptions, it is recommended the [iMate- I] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration - electromagnetic emissions			
The [iMate- I] is intended for use in the electromagnetic environment specified below. The customer or the user of the [iMate- I] should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150KHz to 80MHz 3 V/m 80MHz to 2.5GHz	3V 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the [iMate- I], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation</p>


			<p>distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [iMate- I] is used exceeds the applicable RF compliance level above, the [iMate- I] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [iMate- I].</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the [iMate- I]			
The [iMate- I] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [iMate- I] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [iMate- I] as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2 \sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0,01	/	0.12	0.23
0,1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

WARRANTY REGISTRATION FORM

Item Name: _____

Model Name: _____

Serial No.: _____

Date of Purchase: _____

Name: _____

Address: _____

Phone: _____

Email: _____

Name of Distributor: _____

Authorized Distributors: _____

Stamp and Signature